K071158

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Dr. Jan G. Stannard
134 Old Washington Street
Hanover, MA 02339-1629

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DEVICE
Trade Name: AuraLay Pit & Fissure Sealant
Classification Name: Sealant, Pit and Fissure, and Conditioner
FDA Product Code: 76 EBC, 21 CFR Part 872.3765

JUN - 5 2007

PREDICATE DEVICES:
CosmeSeal Pit and Fissure Sealant
UltraSeal XT Pit and Fissure Sealant and Flowable Composite Kit
Delton Clear Pit and Fissure Sealant Kit

DESCRIPTION AND INTENDED USE:
AuraLay Pit & Fissure Sealant is used to seal the pits and fissures of teeth. AuraLay is comprised of hydrophilic resins and an HLB composition of fillers. Together these provide optimum properties for sealing and excellent tooth wetting. AuraLay has an extremely high compressive strength. This strength combined with excellent sealing and great esthetics make an excellent choice for sealing of teeth. AuraLay is available in different fluoride concentrations for different patient use.

COMPARISON WITH PREDICATE PRODUCTS:
AuraLay Pit & Fissure Sealant is substantially equivalent in design, composition and intended use to the products listed above. Please see page 20 for the entire comparison.

SAFETY AND EFFECTIVENESS:
The AuraLay Pit & Fissure Sealant is substantially equivalent in design, composition, performance, intended use and effectiveness to the predicate kit products listed above.

The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR EBC 872.3765.

According to the NIH Technology Assessment conference on *Effects and Side-Effects of Dental Restorative Materials:* "General usage of these materials over about 30 years indicates a high benetif-to-risk ratio...both composites and glass ionomers are relatively trouble-free. There is no evidence of short-term or long-term risk...There is no suspicion of any problems after virtually billions of procedures in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2007

Dr. Jan G. Stannard
President
Denali Corporation
134 Old Washington Street
Hanover, Massachusetts 02339-1629

Re: K071158
Trade/Device Name: AuraLay Pit & Fissure Sealant
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Codes: EBC and LBH
Dated: April 23, 2007
Received: April 26, 2007

Dear Dr. Stannard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

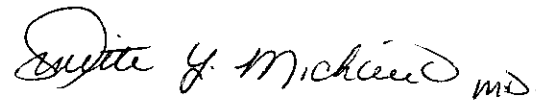
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number K071158
(if known)

Device Name
AuraLay Pit & Fissure Sealant

Indications for Use:

AuraLay Pit & Fissure Sealant is used to seal the pits and fissures of teeth. AuraLay is comprised of hydrophilic resins and an HLB composition of fillers. Together these provide optimum properties for sealing and excellent tooth wetting. AuraLay has an extremely high compressive strength. This strength combined with excellent sealing and great esthetics make an excellent choice for sealing of teeth. AuraLay is available in different fluoride concentrations for different patient use.

Please do not write below this line. Continue on another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K071158

Prescription Use ✓ *or* *Over-The-Counter Use*
(Per 21 CFR 801.109)